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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

May Date JUN 20 2005
Publication Date JUN 21 2005
Certifier R. Ledesma

[Docket No. 2005N-0227]

Update on Leukocyte Reduction of Blood and Blood Components; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Update on Leukocyte Reduction of Blood and Blood Components." The public workshop sponsors are FDA; the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI); and the Office of Public Health and Science (OPHS) in the Department of Health and Human Services. The purpose of the public workshop is to address current issues related to leukocyte-reduced blood and blood components.

Date and Time: The public ~~public~~ workshop will be held on July 20, 2005, from 8 a.m. to 5:30 p.m.

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Friend
6-17-05

Location: The public workshop will be held at the National Institutes of Health, Lister Hill Center Auditorium, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894.

Contact: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3514, FAX: 301-827-2843, e-mail: dawsonr@cber.fda.gov.

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Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Rhonda Dawson (see *Contact*) by July 1, 2005. Because seating is limited, we recommend early registration. Registration at the site on the day of the public workshop will be provided on a space available basis beginning at 7:15 a.m. There is no registration fee for the public workshop.

If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, NHLBI, and OPHS are sponsoring a public workshop entitled "Update on Leukocyte Reduction of Blood and Blood Components." The workshop will include the following topics:

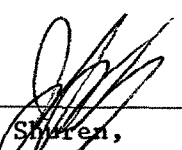
- Leukoreduction in targeted and non-targeted recipients;
- Current data on the potential advantages and hazards of providing leukocyte-reduced blood and blood components;
- A review of observed clinical adverse events and manufacturing failures associated with leukoreduction procedures;
- FDA's current considerations for regulatory standards for leukocyte-reduced components and approaches to quality control testing; and
- New scientific developments in filtration, including developing technologies for prion removal from blood components.

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Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857,

approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: 6/14/05
June 14, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

